

OCT 21 2002

FORM PTO-1449/A and B (Modified)

# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

APPLICATION NO.: 09/917,058

ATTORNEY DOCKET NO.: B00801.70258.US

FILING DATE: July 27, 2001

CONFIRMATION NO.: 2028

APPLICANT: Martha M. Murray M.D.

GROUP ART UNIT: 3738

EXAMINER: Brian E. Pellegrino

Sheet 1 of 3

## **U.S. PATENT DOCUMENTS**

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
BP	B1	4,458,678		Yannas et al.	07/10/1984
	B2	4,578,067		Cruz	03/25/1986
	B3	4,808,570		Michaeli	02/28/1989
	B4	4,955,893		Yannas et al.	09/11/1990
	B5	5,171,273		Silver et al.	12/15/1992
	B6	5,206,023		Hunziker	04/27/1993
	B7	5,655,546		Halpern	08/12/1997
	B8	5,713,374		Pachence et al.	02/03/1998
	B9	5,749,895		Sawyer et al.	05/12/1998
	B10	6,171,610		Vacanti et al.	01/09/2001
BP	B11	09/594,295		Murray	File date: 06/15/2000

## **FOREIGN PATENT DOCUMENTS**

Examiner's Initials	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			
BP	B12	WO	8500511	A1	Medlen	02/14/1985	Y
	B13	WO	9213565	A1	Shaw	08/20/1992	Y
	B14	WO	9321857	A1	Regen Biologics, Inc.	11/11/1993	Y
	B15	WO	9525550	A1	Organogenesis, Inc.	09/28/1995	Y
BP	B16	EP	0295721	A2	Harvard College	12/21/1988	Y

## **OTHER ART — NON PATENT LITERATURE DOCUMENTS**

Examiner's Initials	Cite No.	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
BP	B17	BUCK, "Regeneration of Tendon," 66(1) <i>J. Pathol. Bacteriol.</i> 1-18 (1953)	Y
	B18	MARSHALL et al., "The Anterior Cruciate Ligament: A Technique of Repair and Reconstruction," 143 <i>Clin. Orthop.</i> 97-106 (September 1979)	Y
	B19	FRANK et al., "Natural History of Healing in the Repaired Medical Collateral Ligament," 1(2) <i>J. Orthop. Res.</i> 179-188 (1983)	Y
	B20	YANNAS, et al., "Polymeric template facilitates regeneration of sciatic nerve across 15-millimeter gap," 8 <i>Trans. Soc. Biomater.</i> 146 (1985)	Y
	B21	YANNAS, Collagen Volume 3, <i>Biotechnology</i> , Nimni Ed., p. 87-115 (CRC Press, Boca Raton, Florida, 1989)	Y
	B22	YANNAS et al., "Synthesis and characterization of a model extracellular matrix that induces partial regeneration of adult mammalian skin," 86 <i>Proc. Natl. Acad. Sci USA</i> 933-937 (February, 1989)	Y
	B23	KATO et al., "Formation of continuous collagen fibres: evaluation of biocompatibility and mechanical properties," 11 <i>Biomaterials</i> 169-175 (April, 1990)	Y
BP	B24	NOYES et al., 72A(8) <i>J. Bone Joint Surg.</i> 1125-1136 (September 1990)	Y

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Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
SP ↑	B25	✓ STONE et al., "Future Directions: Collagen-Based Prostheses for Meniscal Regeneration," 252 <i>Clinical Orthopaedics and Related Research</i> 129-135 (March, 1990)	Y
	B26	✓ HEFTI et al., "Healing of the Transected Anterior Cruciate Ligament in the Rabbit," 73A (3) <i>J. Bone Joint Surg.</i> 373-383 (March, 1991)	Y
	B27	✓ GEIGER et al., "An in vitro assay of anterior cruciate ligament (ACL) and medial collateral ligament (MCL) cell migration," 30(3) <i>Connect Tissue Res.</i> 215-224 (1994)	Y
	B28	✓ LOUIE, L. K., et al., "Development of a collagen-GAG copolymer implant for the study of tendon regeneration," M331 <i>Mat. Res. Soc. Symp. Proc.</i> 19-24 (1994)	Y
	B29	✓ SPINDLER et al., "Comparison of collagen synthesis in the peripheral and central region of the canine meniscus," 303 <i>Clinical Orthopaedics</i> 256-263 (June, 1994)	Y
	B30	✓ TROXEL, "Delay of skin wound contraction by porous collagen-GAG matrices," (Ph. D. Thesis, Massachusetts Institute of Technology, 1994) (on file with the MIT Library)	Y
	B31	✓ ARENDT and DICK, "Knee injury patterns among men and women in collegiate basketball and soccer," 23(6) <i>Am. J. Sports Med.</i> 694-701 (1995)	Y
	B32	✓ DEIE et al., "High intrinsic healing potential of human anterior cruciate ligament," 66(1) <i>Acta. Orthop. Scand.</i> 28/32 (1995)	Y
	B33	✓ FORD et al., "Autologous Collagen Vocal Fold Injection: A Preliminary Clinical Study," 105 <i>Laryngoscope</i> 944-948 (September, 1995)	Y
	B34	✓ SCHMIDT et al., "Effect of growth factors on the proliferation of fibroblasts from the medial collateral and anterior cruciate ligaments," 13(2) <i>J. Orthop. Res.</i> 184-190 (1995)	Y
	B35	✓ SPINDLER et al., "Regional mitogenic response of the meniscus to platelet-derived growth factor (PDGF-AB)," 13(2) <i>J. Orthop. Res.</i> 201-207 (1995)	Y
	B36	✓ WEADOCK et al., "Physical crosslinking of collagen fibers: comparison of ultraviolet irradiation and dehydrothermal treatment," 29 <i>J. Biomed. Mater. Res.</i> 1373-1379 (1995)	Y
	B37	✓ DESROSIERS et al., "Proliferative and matrix synthesis response of canine anterior cruciate ligament fibroblasts submitted to combined growth factors," 14(2) <i>J. Orthop. Res.</i> 200-208 (1996)	Y
	B38	✓ DYE, "The Future Of Anterior Cruciate Ligament Restoration," 325 <i>CLIN. Orthop.</i> 130-139 (1996)	Y
	B39	✓ FARYNIARZ, et al., "Myofibroblasts in the healing lapine medial collateral ligament: possible mechanisms of contraction," 14(2) <i>J. Orthop. Res.</i> 228-237 (1996)	Y
	B40	✓ Guidance document for testing biodegradable polymer implant devices, Division of General and Restorative Devices, Center for Devices and Radiological Health, U.S. Food and Drug Administration (April 20, 1996)	Y
	B41	✓ JACKSON et al., "Biologic remodeling after anterior cruciate ligament reconstruction using a collagen matrix derived from demineralized bone: an experimental study in the goat model," 24(4) <i>Am. J. Sports Med.</i> 405-414 (July- August 1996)	Y
	B42	✓ MASUR et al., "Myofibroblasts differentiate from fibroblasts when plated at low density," 93(9) <i>Proc. Nat'l Acad. Sci. USA</i> 4219-4223 (April, 1996)	Y
	B43	✓ MURRAY et al., "Migration of human anterior cruciate ligament fibroblasts into porous collagen-GAG matrices in vitro," 24 <sup>th</sup> Annual Meeting of the Society for Biomaterials, April 22-26, 1996, San Diego, CA P.463	Y
	B44	✓ SPINDLER et al., "Patellar tendon and anterior cruciate ligament have different mitogenic responses to platelet-derived growth factor and transforming growth factor Beta," 14(4) <i>J. Orthop. Res.</i> 542-546 (1996)	Y
	B45	✓ Draft guidance document for the preparation of free market notification [510(K)] Applications for Orthopedic Devices, U.S. Food and Drug Administration (July 16, 1997)	Y
	B46	✓ KAWAMOTO et al., "Selective migration of alpha-smooth muscle actin-positive myofibroblasts toward fibronectin in the Boyden's blindwell chamber," 93(4) <i>Clin. Sci.</i> 355-362 (1997)	Y
	B47	✓ LOUIE, "Effect of a porous collagen-glycosaminoglycan copolymer on early tendon healing in a novel animal model," (Ph.D. Thesis, Massachusetts Institute of Technology, 1997) (copy on file with the MIT Library)	Y
	B48	✓ LOUIE, L. K. et al., "Healing of tendon defects implanted with a porous collagen-GAG matrix: histological evaluation," 3(2) <i>Tissue Eng'g</i> 187-195 (1997)	Y
	B49	✓ STONE et al., "Regeneration of Meniscal Cartilage with Use of a Collagen Scaffold," 79A(12) <i>J. Bone and Joint Surg.</i> 1770-1777 (December 1997)	Y
	B50	✓ WITKOWSKI et al., "Migration and Healing of Ligament Cells under Inflammatory Conditions," 15(2) <i>J. Orthop. Res.</i> 269-277 (1997)	Y
	B51	✓ YANNAS, "Models of Organ Regeneration Processes Induced by Templates," <i>Bioartificial Organs: Science, Medicine, and Technology</i> , Prokop et al. Ed., pp. 280-293 (The New York Academy of Sciences, New York, NY	Y

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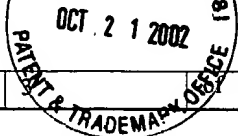
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BP		1997)	
	B52	CHAMBERLAIN, "Long term functional and morphological evaluation of peripheral nerves regenerated through degradable collagen implants," (M.S. Thesis, Massachusetts Institute of Technology, 1998) (copy on file with the MIT library)	Y
	B53	CHAMBERLAIN, "Collagen-GAG Substrate Enhances the Quality of Nerve Regeneration through Collagen Tubes up to Level of Autograft," 154(2) <i>Experimental Neurology</i> 315-329 (December, 1998)	Y
	B54	CHAMBERLAIN et al., "Early peripheral nerve healing in collagen and silicone tube implants: myofibroblasts and the cellular response," 19 <i>Biomaterials</i> 1393-1403 (1998)	Y
	B55	STEVENSON, "Gender differences in knee injury epidemiology among competitive alpine ski racers," 18 <i>Iowa Orthop. J.</i> 64-66 (1998)	Y
	B56	TORRES, "Effects of modulus of elasticity of collagen sponges on their cell-mediated contraction in vitro," M. S. Thesis, Massachusetts Institute of Technology (1998) (copy on file with the MIT Library)	Y
	B57	ANSETH et al., "Polymerizable degradable polyhydrides with osteocompatibility," 17(2) <i>Nature Biotechnol.</i> 166-159 (February 1999)	Y
	B58	FERBER, "Lab Grown Organs Take Shape," 284(5413) <i>Science</i> 422-425 (April 16, 1999)	Y
	B59	FERBER, "Tissue Engineering: From the Lab to the Clinic," 284(5413) <i>Science</i> 422-425 (April 16, 1999)	Y
	B60	GWINN et al., "Relative general incidence of anterior cruciate ligament injury at a military service academy," 66 <sup>th</sup> Annual Meeting of Amer. Acad. of Orthop. Surg., Anaheim, California (1999)	Y
	B61	MURRAY et al., "Fibroblast distribution in the anteriomedial bundle of the human anterior cruciate ligament: The presence of alpha smooth muscle actin-positive cells," 17(1) <i>J. Orthop. Res.</i> 18-27 (1999)	Y
	B62	MURRAY et al., "The migration of human anterior cruciate ligament fibroblasts into porous collagen-GAG matrices in vitro," 45 <sup>th</sup> Annual Meeting, Orthopaedic Research Society, Anaheim, California (February 1-4, 1999)	Y
	B63	NIKLASON et al., "Functional arteries grown in vitro," 284(5413) <i>Science</i> 489-493 (April 16, 1999)	Y
	B64	PETER et al., "Synthesis of poly(propylene fumarate) by acylation of propylene glycol in the presence of a proton scavenger," 10(3) <i>J. Biomater. Sci. Polym. Ed.</i> 363-373 (1999)	Y
	B65	SUGGS et al., "Platelet adhesion on a bioresorbable poly(propylene fumarate-co-ethylene glycol) copolymer," 29(7) <i>Biomaterials</i> 683-690 (1999)	Y
	B66	MURRAY et al., "Migration of cells from human anterior cruciate ligament explants into collagen-glycosaminoglycan scaffolds," 18(4) <i>J. Orthop. Res.</i> 557-564 (2000)	Y
	B67	MURRAY et al., "Histological changes in the human anterior cruciate ligament after rupture," 82A(10) <i>J. Bone Joint Surg.</i> 1387-1397 (2000)	Y
	B68	MURRAY et al., "Migration of cells from ruptured human anterior cruciate ligament explants into collagen-GAG matrices," Proceedings of the Sixth World Biomaterials Congress, 2000; Kamuela, Hawaii	Y
	B69	MURRAY et al., "The effect of ruptured human anterior cruciate ligament histology on cell interactions with a CG scaffold," Davos Tissue Engineering Workshop, 2000; Davos, Switzerland	Y
	B70	QU et al., "Outgrowth of chondrocytes from human articular cartilage explants, and expression of alpha-smooth muscle actin," 18 <i>Wound Repair and Regeneration</i> 383-391 (September - October 2000)	Y
	B71	MURRAY et al., "Differences in the outgrowth of cells from explants from the proximal and distal human ACL and response to TGF-B1," Transactions of the 47 <sup>th</sup> Annual Meeting of the Orthopaedic Research Society, 2001 Feb. 25-28; San Francisco, CA	Y
	B72	MURRAY et al., "The effects of selected growth factors on human ACL cell interactions with 3-D collagen-GAG scaffolds," Transactions of the 47 <sup>th</sup> Annual Meeting of the Orthopaedic Research Society, 2001 Feb. 25-28; San Francisco, CA	Y
BP	B73	MURRAY et al., "The migration of cells from the ruptured human anterior cruciate ligament into collagen-glycosaminoglycan regeneration templates in vitro," 22 <i>Biomater.</i> 2393-2402 (2001)	Y

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#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.